## REMARKS

The following remarks are in further response to the Examiner's Final Office Action mailed on August 10, 2005 and Applicants' interview with Examiner Zachariah Lucas on August 16, 2006. Claims 2, 9 and 23 have been canceled; and claims 16–20 withdrawn. Claims 1, 5, 6, 10, 21, 22, 24, and 25 are amended. Claims 1, 3-8, 10–22, and 24-26 are pending.

### I. Interview with Examiner

Applicants express appreciation to Examiner Lucas for conducting an in-person interview with Applicants on August 16, 2006. During the interview Applicants discussed the issues raised by the Examiner in the Office Action mailed August 10, 2005, details of which are described in the following sections.

### II. Rejection under 35 U.S.C. §103(a)

Claims 1-13 and 15 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Davis (U.S. Patent No. 5,610,077) in view of Glaunsinger et al. (2000) (Oncogene 19:5270-5280) and Bleul (U.S. Patent No. 5,753,233). In addition, claim 14 is rejected under 35 U.S.C. §103(a) as being unpatentable over Davis in view of Bleul and Glaunsinger et al. and further in view of Kehmeier et al. (2002) (Virology 299:72-87).

As discussed in the interview and in Applicants' response to the Final Office Action filed on August 8, 2006, none of the cited references, each alone or in combination, teaches or suggests the claimed method or system for detecting the presence of an oncogenic HPV in a sample by using a PDZ domain polypeptide of less than 1000 amino acids in length and comprising the amino acid sequence of MAGI-1 PDZ domain 2. First, Davis does not teach or suggest detection of an oncogenic strain of HPV, let alone teaches or suggests detection of an oncogenic strain of HPV by using a polypeptide comprising a PDZ domain 2. Second, Bleul merely discusses serum-reactive epitopes on HPV that could be used to detect HPV 18 E6 protein in blood serum. Finally, Glaunsinger et al. merely describes experiments showing that in the cell, the full-length MAGI-1 is

a target for HPV E6 for degradation. Nowhere does this reference teach or suggest detection of oncogenic HPV by using a PDZ polypeptide of less than 1000 amino acids in length and comprising the amino acid sequence of MAGI-1 PDZ domain 2.

In the Office Actions, the Examiner made of record a publication by Thomas et al. which was published in *Oncogene* on September 6, 2001, vol. 22, pp. 5431-5439. As discussed during the interview, Thomas et al. was published *after* the filing date August 3, 2001 of Provisional Application Serial No. 60/309,841 to which the instant application claims priority. As described in the 60/309,841 Application and provided to the Examiner during the interview, Applicants demonstrated that a large number of PDZ polypeptides bind to different PDZ ligands (PLs), such as an E6 protein from oncogenic HPV. See Table 2, and the legend of Table 2 on pp. 18-19. For example, as shown in Example 3, pp. 87-88, and Table 2, page 99, left panel, a PDZ domain 2 of BAI-1 binds with high affinity to E6 from oncogenic HPV strain 66. At the time of filing the 60/309,841 Application, MAGI-1 was called BAI associated protein, or Brain Angiogenic Inhibitor associated proteins. As evidenced in Table 4 on page 103, BAI-1 has the same Genbank Accession (GI) No. 3370997 and amino acid sequence as MAGI-1 listed in Table 2, page 32 of the instant application. In the 60/309,841 Application Applicants also demonstrated that because the carboxy-terminus of the E6 protein from oncogenic strains HPV16, 18, and 31 (T-Q-V/L), and 66 (ESTV), match the consensus PDZ binding motif (pp. 87-88), oncogenic strains HPV16, 18, and 31 would bind to a PDZ domain 2 of BAI-1 (or MAGI-1). Thus, the claimed invention is entitled to the priority of the 60/309,841 Application. Thomas et al. should not be considered as prior art against the claimed invention.

In view of the distinct structural and functional differences between the claimed invention and the methods disclosed in the cited references, a prima facie case of obviousness has not been established under 35 U.S.C. §103(a). Withdrawal of the rejection is therefore respectfully requested.

## III. Obviousness-Type Double Patenting

Claims 1-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting in view of claims co-pending patent application 10/847,818.

As discussed during interview, independent claims 1, 6 and 10 as amended are patentably distinct from the claims of 10/847,818 because the instant claims recite "a PDZ domain polypeptide of less than 1000 amino acids in length and comprising the amino acid sequence of MAGI-1 PDZ domain 2." These elements are not present in and are not reasonably suggested by the claims of 10/847,818. Thus, the claims of these two applications are patentably distinct from each other.

In addition, the instant application has an earlier filing date, July 29, 2003, than that of the 10/847,818 Application, May 17, 2004. Pursuant to MPEP 804 IB1, "[i]f a 'provisional' nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier-filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer."

As such, Applicants respectfully request the Examiner to withdraw the nonstatutory obviousness-type double patenting rejection.

## CONCLUSION

In light of the amendments and remarks set forth above, Applicants earnestly believe that the pending claims are in condition for allowance, and respectfully solicit the Examiner to expedite prosecution of this patent application to issuance. Should the Examiner have any questions, the Examiner is encouraged to telephone the undersigned.

The Commissioner is authorized to charge any additional fees that may be required, including petition fees and extension of time fees, or credit any overpayment to Deposit Account No. 23-2415 (Attorney Docket No. 31470-701.501).

Respectfully submitted,

Date: Aug. 18, 2006 By: _____

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